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PATENT

REMARKS

Claims 1-30, 113-119, and 136-148 are currently pending. New claims 149-152 have been added. Claims 144 and 145 have been withdrawn as directed to a non-elected invention. Claims 1, 9, 10, 113, 136-140, 146, and 148 have been amended. Claims 1, 9, 10, 113, 136-140, and 148 have been amended to change "wild type" to "non-attenuated," as discussed below. Support for the amendment to claim 146 can be found in the specification at page 35, lines 5-6. Support for new claims 149-152 can be found in the specification at page 35, lines 7-8.

Election/Restriction

The Office has stated that claims 144 and 145 (added in Amendment B, which was filed February 18, 2004) are directed to an invention that is independent or distinct from the invention originally claimed. Claims 144 and 145 have been withdrawn.

Objections to the Specification

The Office has objected to the specification on pages 41 under MPEP §608.01 as containing an embedded hyperlink. In Amendment B, filed February 18, 2004, applicants amended the paragraph beginning on page 41, line 12 of the specification to remove the embedded hyperlink. In light of this amendment, applicants respectfully submit that the hyperlink in the paragraph beginning on page 41, line 12 of the specification has already been removed. Applicants thus request withdrawal of this objection to the specification.

The Office has also objected to the specification on page 30 as containing a trademark. Applicants assume the Office is referring to the term "Antifoam A". It is the understanding of the applicants that "Antifoam A" is generic and not a trademark, and therefore no amendment to the specification is required.

Rejections under 35 U.S.C. §112, second paragraph

Reconsideration is requested of the rejection of claims 136-143 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, the Office has objected to the use of the term "rate sufficient."

Claim 136 has been amended to remove the term "rate sufficient" and to read "...introducing an oxidizing agent into said medium so that the average dissolved oxygen content during sporulation is maintained at at least 30% of saturation..."[1] In light of this amendment, applicants submit that claim 136, and dependent claims 137-143 are not indefinite, and request withdrawal of the rejection of claims 136-143 under 35 U.S.C. §112, second paragraph.

Rejections under 35 U.S.C. §102(a)

Reconsideration is requested of the rejection of claims 1-25, 29-30, 113-119, 136-142, and 146-148 under 35 U.S.C. §102(a) as anticipated by Conkle, et al. (WO 00/50072).

Claims 1, 9, 10, 113, 136, and 148

Amended claims 1, 9, and 10 are directed to a composition for the prevention or control of coccidiosis. The composition comprises viable non-attenuated sporulated oocysts of at least one species of protozoa known to cause coccidiosis, wherein the composition is sterile. The composition of claim 1 contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate. The composition of claim 9 contains at least about 300 oocysts per milliliter and less than

[1] Support for this amendment can be found on page 30, lines 14-22 of the Specification.

about 0.002% by weight of alkali metal dichromate. The composition of claim 10 contains less than about 5.0×10^{-3} µg of alkali metal dichromate per oocyst.

Amended claim 113 is directed to a kit for the prevention or control of coccidiosis. The kit comprises: (1) a composition containing sterile, viable, non-attenuated sporulated oocysts of at least one species of protozoa known to cause coccidiosis and less than about 0.8% by weight of alkali metal dichromate; and (2) instructions for administration of the composition to an animal.

Amended claim 136 is directed to a composition for the prevention or control of coccidiosis. The composition comprises viable non-attenuated sporulated oocysts of at least one species of protozoa known to cause coccidiosis, and is substantially free of alkali metal dichromate.

Amended claim 148 is directed to a composition for the prevention and treatment of coccidiosis. The composition comprises a pharmaceutically acceptable carrier, diluent, or excipient; and viable, non-attenuated, sporulated oocysts of at least one species of protozoa known to cause coccidiosis; wherein the sporulated oocysts are sterile, and the composition is substantially free of potassium dichromate.

As previously noted, claims 1, 9, 10, 113, 136-140, and 148 have been amended to change "wild type" to "non-attenuated." Support for this amendment can be found in the Specification at page 11, line 26 which states that the oocysts of the present invention are derived from wild type oocysts, since oocysts that are "derived from wild type oocysts" clearly encompass non-attenuated oocysts. Further support is found throughout the specification in various passages that state that the compositions of the present invention comprise wild type oocysts[2] since, as will be recognized by those skilled in the art, wild type oocysts are by their very nature non-attenuated.[3]

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[2] *See, e.g.*, Specification at p. 46, ln. 21 and p. 47.

[3] To attenuate an oocyst, by definition, means to weaken or reduce its virulence. Since wild type oocysts refer to the typical characteristic of the oocyst as it occurs in nature, such oocysts have not been manipulated to weaken or reduce their virulence; i.e., they are

MPEP §2131 states that a claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

Independent claims 1, 9, 10, 136, and 148 are all directed to compositions for the prevention or control of coccidiosis comprising viable non-attenuated sporulated oocysts. In claim 113, directed to a kit for the prevention or control of coccidiosis comprising a composition and instructions, the composition contains sterile, viable, non-attenuated sporulated oocysts. Conkle, et al. describe the preparation of a suspension comprising sporulated oocysts. Although Conkle, et al. indicate that the oocysts used therein may be of a variety of different species of *Eimeria*, including *E. maxima, E. mitis, E. tenella, E. acervulina, E. brunetti, E. necatrix,* and *E. praecox*, Conkle, et al. do not indicate what type of oocysts are used. Rather, Conkle, et al. merely state that the oocysts "may be obtained from various sources including purified suspensions, intestinal linings, and fecal suspensions."[4] Specifically, Conkle, et al. do not describe the use of non-attenuated oocysts.[5] Since the type of oocysts is not specified, Conkle, et al. could have been using

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non-attenuated.

[4] WO 00/50072, p. 4, ln. 37-38.

[5] Other references actually teach away from using non-attenuated oocysts. For example, U.S. Patent No. 5,055,292 (Reference No. 3, cited in the IDS submitted Jan. 16, 2002) discloses coccidiosis vaccines comprising attenuated precocious strains of *Eimeria*, and states that using attenuated oocysts avoids some of the problems associated with unattenuated live vaccines, such as dosage problems, and problems associated with potential pathogenic effects of administering unattenuated vaccines. *Id.* at col. 1, ln. 33-47 and col. 2, ln. 44-52. *See also* U.S. Patent No. 4,438,097, col. 1, ln. 47-51n (Reference No. 1, cited in the IDS submitted Jan. 16, 2002). Since Conkle, et al. do not specify the type of oocysts, and other references actually teach away from using non-attenuated oocysts, it would also not be obvious to use non-attenuated oocysts in the compositions of Conkle, et al. It is now established that obviousness must be evaluated against the entire background of the art, not in view of first one and then another of isolated teachings that may be selected with the benefit of hindsight once applicant's invention is known; In re Kuderna, 165 USPQ 575 (CCPA 1970). *See also*, Panduit Corp. v. Dennison Mfg. Co., 227 USPQ 339 (Fed. Cir.

other types of oocysts, such as attenuated strains. Conkle, et al. can thus not be said to describe each and every element of claims 1, 9, 10, 113, 136, and 148.

With regard to claim 113, the Office has also indicated that a package insert, such as instructions, does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. The Office has further indicated that "instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly no functional relationship exists between the instructions for use and the composition." "[T]he instructions for use included in composition constitute an 'intended use' for that composition."

Applicants submit that the instructions in the kit of claim 113 constitute more than a mere intended use; they are functionally related to the composition, and therefore should be given patentable weight.[6] Claim 113 is directed to a kit for the prevention or control of coccidiosis, comprising a composition containing sterile, viable, non-attenuated sporulated oocysts and less than about 0.8% by weight of alkali metal dichromate, and instructions for administration of the composition to an animal; claim 113 is not directed to either the composition or instructions alone. Furthermore, the vaccine compositions of the present invention may be administered by a variety of routes, and may require dilution before administration.[7] The instructions in claim 113 are for administration of the

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1985).

[6] "Under section 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole." *In re Gulack*, 217 USPQ 401, 403 (Fed. Cir. 1983). Furthermore, "[t]he fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination." *In re Miller*, 164 USPQ 46, 49 (C.C.P.A. 1969).

[7] "The vaccine may be concentrated, requiring dilution before administration, or the vaccine may be ready for administration. The concentrated embodiment of the instant

composition to an animal, and are thus functionally related to the composition since they allow the user of the kit to gain the additional benefit of a properly prepared and administered composition.

In addition, Conkle, et al. do not disclose a kit comprising a composition containing sporulated oocysts and instructions for administration of the composition to an animal. Conkle, et al., as previously discussed, do not even describe a composition with viable, non-attenuated sporulated oocysts, as required by claim 113.

In light of the foregoing, applicants respectfully request withdrawal of the rejection of claims 1, 9, 10, 113, 136, and 148 under 35 U.S.C. § 102(a). Claims 2-8, 14-25, and 29-30 are either directly or indirectly dependent on claim 1; claims 11-13 are either directly or indirectly dependent on claim 10; claims 114-119 are either directly or indirectly dependent on claim 113; and claims 137-142 are either directly or indirectly dependent on claim 136. These claims are patentable for the same reasons as the independent claim from which they depend.

Claims 23 and 142

Claims 23 and 142 are indirectly dependent on claims 1 and 136, respectively, and are thus patentable for the same reasons as set forth above for claims 1 and 136. Furthermore, the Office has appeared to misinterpret claims 23 and 142. The Office has stated that "[c]laim limitations such as 'the composition ameliorates a decline or decrease in post-challenge performance' ... are being viewed as inherent and as a limitation of intended use."

Claim 23 (dependent on claim 14) and claim 142 (dependent on claim 137) are directed to compositions which further comprise, as a component thereof, a composition

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invention may be diluted with any suitable diluent to concentrations suitable for various forms of administration, including intra-yolk sac administration, per os, oral gavage, delivery via spray cabinet, or top-fed via spray onto food, such as OASIS Hatchling Supplement." Specification, p. 46, ln. 15-20.

which ameliorates a decline or decrease in post-challenge performance (i.e. an ameliorating composition).[8] The phrase "which ameliorates a decrease [or decline] in post-challenge performance" does not specify a mere property of the composition as a whole, but instead defines an additional component of that composition by a functional characteristic which that component possesses. Such "ameliorating composition" is a component that is included in the sporulated oocyst-containing compositions of claims 14 and 137, respectively, to provide the compositions claimed in claims 23 and 142. The phrase "which ameliorates a decrease [or decline] in post-challenge performance" thus does not refer to a mere intended use, but rather, to an ameliorating composition which is a component of the composition of claims 23 and 142.

In addition, the Office has provided no evidence to support its stated conclusion that the claim limitation "the composition ameliorates a decline or decrease in post-challenge performance" is inherent in the cited reference. It is respectfully submitted that a finding of inherency cannot be based on *mere assumptions* by the Office. Rather, to establish inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."[9] Furthermore, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."[10] In contrast to the compositions of claims 23 and 142, an ameliorating composition is not

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[8] See Specification, p. 44 for a description of compositions which ameliorate a decrease in post challenge performance.

[9] MPEP § 2112 (citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

[10] MPEP §2112 (citing *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993)). MPEP §2112 also states "[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

present as a component of the sporulated oocyst suspensions of Conkle, et al. Rather, the oocysts described in Conkle, et al. are merely suspended in an oxidant during sporulation, and then may be washed using water following sporulation. Consequently, the compositions of Conkle, et al. cannot be said to *necessarily* comprise any vaccine composition comprising viable, non-attenuated sporulated oocysts, much less any vaccine composition further comprising a composition that ameliorates a decrease or decline in post-challenge performance. Claims 23 and 142 are thus patentable for this further reason.

Claim 139

Claim 139 depends indirectly on claim 136 and is thus patentable for the same reasons as set forth above for claim 136. In addition, the Office has appeared to misinterpret claim 139. The Office has stated that "[c]laim limitations such as...'a ratio is defined by the minimum immunizing dose and amount determined by storage h[alf]-life determinations' are being viewed as inherent and as a limitation of intended use."

Claim 139 (dependent on claim 137) is directed to a composition wherein the composition comprises viable non-attenuated sporulated oocysts of *E. acervulina, E. maxima,* and *E. tenella* in a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations. The phrase "in a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" does not specify a mere intended use of the composition as a whole, but instead defines the ratio and amount of *E. acervulina, E. maxima,* and *E. tenella* sporulated oocysts that are present in the composition. For example, the specification indicates that the sporulated oocysts are present in a composition in a number sufficient to comprise a minimum immunizing dose.[11] Since a certain number of sporulated oocysts cease to be

[11] "The combined species of sporulated oocysts are present in a number sufficient to comprise the minimum number of sporulated oocysts required to comprise an effective dose for immunizing purposes." Specification, p. 45, ln. 18-21.

functional as they age, the minimum number of sporulated oocysts of each *Eimeria* species in the composition may be determined using the minimum immunizing dose and the storage half-life of the sporulated oocysts.[12]

In addition, the Office has provided no evidence to support its stated conclusion that the claim limitation "a ratio is defined by the minimum immunizing dose and amount determined by storage h[alf]-life determinations" is inherent in the cited reference. As previously discussed, to establish inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."[13] "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."[14] Conkle, et al. do not describe any ratio of *E. acervulina*, *E. maxima*, and *E. tenella* sporulated oocysts present in their composition. As previously discussed, Conkle, et al. merely state that the coccidial oocysts can be *E. maxima*, *E. mitis*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. necatrix*, *E. praecox*, and mixtures thereof, but do not disclose any ratio of oocysts. Furthermore, Conkle, et al. do not discuss the aging of sporulated oocysts or determining a suitable amount of oocysts by storage half-life determinations. Consequently, the

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[12] "The number of sporulated oocysts per dose is further determined by the estimated half-life of the sporulated oocysts in the storage composition claimed herein. As the sporulated oocysts age a certain number cease to be functional...Therefore, a minimum amount of a single species or combination of sporulated oocysts is added to the compositions for consumption that will result in the minimum immunizing dose computed as a function of half-life determinations." *Id.* at ln. 21-27.

[13] MPEP § 2112 (citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

[14] MPEP §2112 (citing *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993)). MPEP §2112 also states "[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

compositions of Conkle, et al. cannot be said to *necessarily* comprise sporulated oocysts of *E. acervulina*, *E. maxima*, and *E. tenella* in a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations, as required by claim 139. Conkle, et al. can thus not be said to describe all the limitations of claim 139, and claim 139 is thus also patentable for this further reason.

Claims 146, 147, and 149-152

Claims 146 and 147, and new claims 149-152 are likewise submitted to be patentable under 35 U.S.C. §102(b) over Conkle, et al. Claims 146 and 147 are directed to compositions comprising viable sporulated oocysts of at least one species of protozoa known to cause coccidiosis. In amended claim 146, the oocysts have been separated by tangential flow filtration from an aqueous sporulation medium using a filter membrane with a pore size such that sporulated oocysts can not enter the pores, but bacteria can pass through the pores. In claim 147, the composition is sterile, and the oocysts have been separated by tangential flow filtration from an aqueous medium containing bacterial contaminants. Significantly, the compositions of claims 146 and 147 comprise oocysts that have been separated by tangential flow filtration from bacterial contaminants.

For example, as amended, claim 146 states that the oocysts have been separated by tangential flow filtration from an aqueous sporulation medium using a filter membrane with a pore size such that sporulated oocysts can not enter the pores, but bacteria can pass through the pores.[15] Because the pore size of the filter membrane used during tangential flow filtration is large enough to allow bacteria to pass through, the oocysts retained by the filter membrane have been separated from both viable and non-viable contaminants, such as bacteria. The resulting oocyst containing composition of claim 146 thus contains a much lower amount of bacterial contaminants (both viable and non-

[15] Support for this claim may be found in the specification, p. 35, lines 5-6 ("The pore size of the filter membrane should be small enough so that sporulated oocyst cannot enter the pores, but large enough to allow bacteria to pass through.").

viable) than would be present in the composition were the pore size small enough to retain bacteria as well as oocysts.

The same is true for claim 147, which is directed to a composition comprising oocysts that have been separated by tangential flow filtration from an aqueous medium containing bacterial contaminants. Because the oocysts of claim 147 have been separated from an aqueous medium containing bacterial contaminants, the pore size used during the tangential flow filtration must necessarily be such that the oocysts are retained, while bacterial contaminants pass through the pores; otherwise separation would not occur. Consequently, the composition of claim 147 contains a much lower amount of viable and non-viable bacterial contaminants than would be present in a composition comprising oocysts that were not separated by tangential flow filtration from bacterial contaminants.

Conkle, et al. state that oocysts may be washed following sporulation to reduce the residual oxidant concentration to an acceptable level. The washing may be accomplished by serial washings, preferably by membrane filtration, and more preferably by diafiltration. Serial washing or diafiltration may also be used to reduce the residual oxidant concentration (e.g., the concentration of sodium hypochlorite) in the suspension after bleaching.[16] Significantly, Conkle, et al. do not disclose the use of a filter pore size small enough to prevent sporulated oocysts from entering the pores, but large enough to allow bacteria to pass through the pores. Rather, the only mention in Conkle, et al. of pore size is a statement that in the case of membrane filtration, "the membrane pore size is selected to allow passage of solutes through the membrane while restricting the passage of the oocysts from one side of the membrane to the other."[17] There is no statement or suggestion in Conkle, et al. that the pore size should also be large enough

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[16] "Following bleaching, the bleached suspension is washed, if necessary, to reduce the residual oxidant concentration to an acceptable level." Conkle, et al., p. 8, ln. 33-35.

[17] Conkle, et al., p. 8, ln. 19-20 (emphasis added).

to allow the passage of bacteria, as well as solutes. In fact, such a pore size would not be necessary, since Conkle, et al. are merely washing the oocysts to reduce the residual oxidant concentration to an acceptable level, not to separate the oocysts from bacterial or other contaminants that may be present in the sporulation medium. Consequently, in contrast to the compositions of claims 146 and 147, the compositions of Conkle, et al. do not comprise oocysts that have been separated by tangential flow filtration from bacterial contaminants, including non-viable bacterial contaminants. The composition of Conkle, et al. thus can be said to comprise a greater amount of non-viable bacterial contaminants than the compositions of claims 146 and 147.[18]

As is known to those skilled in the art, the presence of contaminants, such as non-viable bacterial contaminants, in a vaccine composition increases the risk of producing a pyrogenic reaction in a vaccinated animals.[19] Consequently, the compositions of claims 146 and 147 provide an advantage over the compositions of Conkle, et al., in that the lower amount of non-viable bacterial contaminants reduces the risk that animals administered the composition will experience a pyrogenic reaction.

In summary, since Conkle, et al. do not describe or suggest the use of tangential flow filtration in the preparation of their sporulated oocyst suspension, and do not disclose or suggest filtering the oocysts using a filter with a pore size such that oocysts are retained, but bacteria may pass through the pores, the sporulated oocyst suspension of Conkle, et al. would be expected to contain at least more non-viable bacterial contaminants than would the compositions of claims 146 or 147. Thus, Conkle, et al. do not describe each and every element of claim 146 or 147, and specifically, do not

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[18] In fact, Conkle, et al. even recognize that some solids may be present in the final suspension, and give preferred maximum solids size. *Id.* at p. 8, ln. 38 to p. 9, ln. 3 ("[T]he final concentrated encysted protozoa suspension can include a maximum solids size of less than about 200 microns, preferably less than about 25 microns, a salt content of less than about 0.96 percent...and a cyst concentration of about 1 x 10^6 to 2.5 x 10^6 cysts/ml.")

[19] Methods for determining whether a pyrogenic reaction occurs are well known in the art.

describe a composition wherein oocysts have been separated by tangential flow filtration from an aqueous sporulation medium using a filter membrane with a pore size such that sporulated oocysts can not enter the pores, but bacteria can pass through the pores, or from an aqueous medium containing bacterial contaminants, respectively.

Claims 149-152 are either directly or indirectly dependent on claims 146 or 147 and are thus patentable for the same reasons as set forth above for claims 146 and 147.

In light of the foregoing, applicants respectfully request withdrawal of the rejection of claims 1-25, 29-30, 113-119, 136-142, and 146-148 under 35 U.S.C. §102(b), and allowance of these and new claims 149-152.

Rejections under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-30, 113-119, 136-143, and 146-148 under 35 U.S.C. §103(a) as unpatentable over Conkle, et al. (WO 00/50072), in view of Brown, et al. (U.S. Patent No. 6,019,985).

Brown, et al. is apparently relied on primarily as suggesting the incorporation of *P. acnes* into the oocyst containing compositions of Conkle, et al. It is noted that, of the rejected claims, only claims 26-28 and 143 actually require the presence of *P. acnes*. The compositions of claim 23 and 142 further comprise a composition which ameliorates a decline or decrease in post-challenge performance (i.e., an ameliorating composition, as discussed above),[20] but does not affirmatively require *P. acnes*.

In any event, it is respectfully submitted that all of claims 1-30, 113-119, 136-143, and 146-148, and new claims 149-152 are patentable over Conkle, et al., and over any combination of Conkle, et al. with Brown, et al.

Conkle, et al., is described above. Brown, et al. disclose methods for immunization against coccidiosis and other bacterial, viral, or parasitic diseases in

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[20] *P. acnes* is one example of such an ameliorating composition. *See* Specification, p. 44.

poultry. The methods include administering a solution of *Propionibacterium acnes* suspended in a diluent, such as normal saline, to a chick in ovo or following hatching.[21] Other materials, such as antibiotics (e.g. gentamicin, ceftiofur, and erythromycin), vaccines, vitamins, growth media, etc. may also be added to the diluent.[22] Hatched chicks may also be administered an anti-coccidial vaccine, such as IMMUCOX® anticoccidial vaccine or COCCIVAC® anticoccidial vaccine,[23] in combination with the *P. acnes* suspension.

Where a single reference (or a combination of references) is relied on for a §103 rejection, the Office must show: (1) some suggestion or motivation, either in the references themselves, in the knowledge generally available to one of ordinary skill in the art, or in the nature of the problem to be solved[24] to modify the reference or to combine reference teachings; (2) a reasonable expectation of success; and (3) that the prior art reference (or references when combined) teach or suggest all the claim limitations.

As discussed above, Conkle, et al. do not describe or suggest suspensions of non-attenuated sporulated oocysts. Thus, even if one were to add a composition comprising *P. acnes* (e.g. *P. acnes* in a diluent) as taught by Brown, et al. to the sporulated oocyst suspensions of Conkle, et al., as the Office suggests, this combination would not satisfy all the limitations of any of claims 1-30, 113-119, 136-143, or 148. More specifically, the combination of Conkle, et al. and Brown, et al. does not suggest compositions (or kits) for the prevention or control of coccidiosis comprising viable, non-attenuated sporulated oocysts.

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[21] U.S. Patent No. 6,019,985, col. 3-4.

[22] *Id.* at col. 4, ln. 7-14.

[23] *Id.* at ln. 59-67.

[24] Ruiz v. A.B. Chance Co., No. 03-1333 (Fed. Cir. Jan. 29, 2004).

In addition, the Office has also stated that claim limitations such as "the composition ameliorates a decline in post-challenge performance" (claims 23 and 142), and "a ratio is defined by the minimum immunizing dose and amount determined by storage half-life determinations" (claim 139) are being viewed as limitations of intended use. Applicants respectfully submit that such limitations are not limitations of intended use, for the reasons set forth above.

In light of the foregoing, applicants respectfully request withdrawal of the rejection of independent claims 1, 9, 10, 113, 136, and 148 under 35 U.S.C. §103(a). Claims 2-8, and 14-30 are either directly or indirectly dependent on claim 1; claims 11-13 are either directly or indirectly dependent on claim 10; claims 114-119 are either directly or indirectly dependent on claim 113; and claims 137-143 are either directly or indirectly dependent on claim 136. These claims are patentable for the same reasons as the independent claim from which they depend.

Claims 146-147 and new claims 149-152 are likewise submitted to be patentable under 35 U.S.C. §103(a) in light of Conkle, et al. and Brown, et al.

Claims 146 and 147 are directed to compositions comprising viable sporulated oocysts of at least one species of protozoa known to cause coccidiosis. In amended claim 146, the oocysts have been separated by tangential flow filtration from an aqueous sporulation medium using a filter membrane with a pore size such that sporulated oocysts can not enter the pores, but bacteria can pass through the pores. In claim 147, the composition is sterile, and the oocysts have been separated by tangential flow filtration from an aqueous medium containing bacterial contaminants. Significantly, the compositions of claims 146 and 147 comprise oocysts that have been separated by tangential flow filtration from bacterial contaminants.

As previously discussed, Conkle, et al. do not describe or suggest the use of tangential flow filtration in the preparation of their sporulated oocyst suspension, and do not disclose or suggest filtering the oocysts using a filter with a pore size such that

oocysts are retained, but bacteria may pass through the pores. The sporulated oocyst suspension of Conkle, et al. would thus be expected to contain at least more non-viable bacterial contaminants than would the compositions of claims 146 or 147.

Likewise, Brown, et al. do not describe or suggest the use of tangential flow filtration in the preparation of a sporulated oocyst suspension. More specifically, Brown, et al. do not disclose or suggest filtering oocysts using a filter with a pore size such that oocysts are retained, but bacteria may pass through the pores. Thus, there is no motivation in Brown, et al. to perform tangential flow filtration (as in claims 146 or 147) in the preparation of the compositions of Conkle, et al., and the combination of Conkle, et al. and Brown, et al. cannot be said to teach or suggest all the limitations of claims 146 or 147. New claims 149-152 depend either directly or indirectly from claims 146 or 147 and are thus patentable for the same reasons as set forth for claims 146 and 147.

In light of the foregoing, applicants respectfully request withdrawal of the rejection of claims 1-30, 113-119, 136-143, and 146-148 under 35 U.S.C. §103(a), and allowance of these and new claims 149-152.

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CONCLUSION

In light of the foregoing, applicants respectfully request withdrawal of the rejection of claims 136-143 under 35 U.S.C. §112, second paragraph; claims 1-25, 29-30, 113-119, 136-142, and 146-148 under 35 U.S.C. §102(a); and claims 1-30, 113-119, 136-143, and 146-148 under 35 U.S.C. §103(a), and allowance of these and new claims 149-152.

Applicants do not believe that a fee is due in connection with this response. If, however, the Commissioner determines that a fee is due, he is authorized to charge Deposit Account No. 19-1345.

Respectfully submitted,

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